

## **REMARKS**

The claims are 1-3, 5, 8, 9 and 11-14. Claims 1 and 12 are in independent form. Favorable reconsideration and allowance of the subject application are respectfully requested in view of the following comments.

### **REJECTION UNDER 35 U.S.C. § 103**

Claims 1-3, 5, 8, 9 and 11-14 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 6,667,050 (“*Boissonneault et al.*”) in view of U.S. Patent No. 3,619,292 (“*Brouillard et al.*”) or *Boissonneault et al.* and U.S. Patent No. 4,684,534 (“*Valentine*”) in view of *Brouillard et al.* Applicants respectfully traverse these rejections, in view of the comments set forth below.

One of the noteworthy features of Claim 1 is the inclusion of directly compressible dextrose monohydrate.

Applicants have found that the use of directly compressible dextrose monohydrate is important to the formation of the claimed tablet. Directly compressible grades of dextrose monohydrate impart a smooth, creamy texture and fast melt-away to soft tablets that are designed for chewing or dissolving in the mouth prior to swallowing. The use of directly compressible dextrose monohydrate enables the manufacture of tablets without including fats and water soluble binders.

As shown in Exhibit A which is attached to the end of this paper, the results of testing performed by Applicants demonstrate that dextrose monohydrates, such as C\*PHARMDEX 02011 (Glucose Monohydrate) from Cargill or LYCADEX® PF pyrogen-free dextrose monohydrate from Roquette Pharma, when used in tablet formulations, did not produce

acceptable results. In fact, only one tablet out of a possible twenty tablets produced using either source of dextrose monohydrate was acceptable.

On the other hand, when directly compressible dextrose monohydrate is used, e.g., CERELOSE brand of dextrose monohydrate available from Corn Products USA, the tablets produced were chewable and/or dissolved in the mouth prior to swallowing. Exhibit A shows that nine out of ten tablets produced using directly compressible dextrose monohydrate (CERELOSE brand of dextrose monohydrate) were acceptable. Moreover, Applicants have not found any mention of the use of dextrose monohydrate that is directly compressible in making a tablet capable of being chewed or disintegrated in the oral cavity prior to Applicants' invention, as recited in Claim 1.

Also, of noteworthy consideration is the information provided in Exhibit B (obtained from each company's website), which shows that only CERELOSE brand of dextrose monohydrate indicates that it is directly compressible. Neither C\*PHARMDEX 02011 (Cargill) or LYCADEX® PF (Roquette Pharma) state that they are directly compressible forms of dextrose monohydrate.

Applicants again submit that *Boissonneault et al.*, *Brouillard et al.* and *Valentine* are not seen to teach or disclose the use of a directly compressible dextrose monohydrate in chewable tablet formulations. *Boissonneault et al.*, *Brouillard et al.* and *Valentine* all fail to appreciate the difference between dextrose monohydrate and directly compressible dextrose monohydrate. Understanding the distinction enables one to manufacture chewable tables without the use of fats and water soluble binders. As such, Claim 1 is patentable over *Boissonneault et al.*, *Brouillard et al.* and/or *Valentine* whether considered separately or in combination.

Claim 12 is similar to Claim 1 and also includes a directly compressible dextrose monohydrate. For at least the reasons stated above for Claim 1, Claim 12 is patentable over *Boissonneault et al.*, *Brouillard et al.* and/or *Valentine*, whether considered separately or in combination.

Claims 2, 3, 5, 8, 9, 11 and 14 depend from Claim 1, and Claim 13 depends from Claim 12. These claims are also believed to be patentable over the cited references, since they depend from a patentable base claim.

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration and allowance of the claims in the present application.

Applicants' undersigned attorney may be reached in our office by telephone at (732) 524-1767. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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